

## REMARKS

Claims 1-18, 22-25, 30-41, and 57 are pending in the present application. Claims 1 and 39 have been amended. New claim 57 has been added. Support for the new claim and the claim amendments may be found throughout the instant specification and originally filed claims. In particular, support for claim 57 is provided on pages 13 and 28 of the application and in the claims as originally filed. The claim cancelations and amendments should not be construed to be an acquiescence to any of the claim rejections. Rather, the cancelations and amendments to the claims are being made solely to expedite the prosecution of the above-identified application. The Applicants expressly reserve the right to further prosecute claims drawn to canceled or deleted subject matter in subsequent patent applications claiming the benefit of priority to the instant application. 35 USC § 120.

### Claim Rejections under 35 U.S.C. § 102(b)

Claims 39-40 stand rejected under 35 U.S.C §102(b) as being anticipated by U.S. Patent 2,676,961 (“the ’961 patent”). Applicants respectfully traverse this rejection. However, in order to expedite prosecution, claim 39 has been amended to recite “inorganic salt of an analgesic agent.” Support for such amendment may be found throughout the specification and claims as originally filed, including for example, p. 13 ll. 13-21. Applicants therefore respectfully request reconsideration and withdrawal of this rejection based on the ’961 patent.

### Claim Rejections under 35 U.S.C §103(a)

Claims 1-18, 22-25, and 30-41 stand rejected under 35 U.S.C § 103(a) as being unpatentable over U.S. 4,652,563 (“the ’563 patent”) in view of Katzung. Applicants respectfully traverse this rejection. As the Action notes, “’563 teaches a composition that could comprise lidocaine”. Applicants contend that the ’563 patent does not disclose a pharmaceutically acceptable inorganic *salt* of an analgesic agent, as recited in claims 1, 39, 40 and by reference dependent claims 2-18, 30-38 and 41. Nor does the Katzung reference disclose a salt of an analgesic agent and a biocompatible oil.

Because the ’563 patent and the Katzung reference, each alone or in combination, fail to teach all the limitations of independent claims 1, 39 or 41, Applicants submit herein that the

Examiner fails to provide a *prima facie* case of obviousness. Further, as the Examiner knows, and based at least on MPEP 2143, a *prima facie* case of obviousness under 35 U.S.C. 103(a) requires (1) a suggestion or motivation in the references themselves or generally known in the art, to combine the references, (2) a reasonable expectation of success to combine, and (3) a teaching, via the combination, of all the claimed limitations. Applicants respectfully further submit that there no suggestion or motivation in either the '563 patent nor in the Katzung reference to suggest the instantly claimed compositions. Applicants therefore request withdrawal of this rejection.

Claims 39-41 stand rejected under 35 U.S.C § 103(a) as being unpatentable over US 5,288,723 ("the '723 patent"). The Examiner asserts that this patent "teaches an analgesic agent veratridine and its salts as useful in parenteral suspension formulation using sesame oil as the carrier." Applicants respectfully note to the Examiner that the '723 patent does not identify that a salt of veratridine may be used in composition with an oil. Additionally, veratridine is not a caine analgesic agent as recited in claim 41.

Claims 1-18, 22-25, and 30-41 stand rejected under 35 U.S.C § 103(a) as being unpatentable over U.S. 3,105,793 ("the '793 patent") in view of Katzung. Applicants respectfully traverse this rejection. However, in order to expedite prosecution, claims 1 and 39 have been amended to recite the transitional phrase "consisting essentially of." Support for the claim amendment can be found in claim 41 of the application as originally filed.

The Applicants respectfully contend that the '793 patent in view of Katzung does not form the basis of a proper rejection under 35 U.S.C § 103(a) of claims 1-18, 22-25, and 30-41 because neither the '793 patent nor Katzung alone or together teach a pharmaceutical composition consisting essentially of an analgesic agent and biocompatible oil. In fact, the '793 patent teaches away from the use of caine analgesics because the '793 patent teaches at col. 3 ll. 50-52 that the disclosed combination "eliminates the necessity of using potentially harmful cocaine or any of its derivatives, such as procaine." Accordingly, the Applicants respectfully request withdrawal of this rejection.

### FEES

The Applicants believe they have provided for the required fees in connection with the filing of this paper. Nevertheless, the Director is hereby authorized to charge any additional required fee to our Deposit Account, 06-1448.

### CONCLUSION

In view of the foregoing remarks, early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-832-1000.

Respectfully submitted,  
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